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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/783,884	02/14/2001	Christopher J. Berry	57897-5005	3367

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EXAMINER	
JIANG, SHAOJIA A	
ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/783,884	BERRY ET AL.	
	Examin r	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23,34-48 and 52-61* is/are pending in the application.

4a) Of the above claim(s) *1-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34-48 and 52-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *11* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on August 26, 2002 in Paper No. 13 wherein claim 34 has been amended and claims 52-61 are newly submitted. Currently, claims 1-23, 34-48 and 52-61 are pending in this application.

Applicant's remarks with respect to the objection of claims 38-43 made under 37 CFR 1.75 (c) for improper dependent for failing to further limit claim 34 of record in the Office Action dated February 26, 2002 have been fully considered and are found persuasive. Therefore, this objection is withdrawn.

Applicant's amendment filed on August 26, 2002 in Paper No. 13 with respect to the rejection of claims 34-43 made under 35 U.S.C. 112 second paragraph for being incomplete for omitting essential elements of record in the Office Action dated February 26, 2002 have been fully considered and found persuasive to remove the rejection since claim 34 has been amended to add the essential elements. Therefore, the said rejection is withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 34, 36, and 44-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Jandacek (3,865,939, PTO-892) for reasons of record stated in the Office Action dated February 26, 2002.

Jandacek discloses that the edible oil therein is useful in a composition and a method of reducing total serum cholesterol and serum LDL cholesterol and raising serum HDL cholesterol in a human and that this edible oil in the composition with effective amounts of active ingredients is administered in the form of a food product such as cooking, salad oil or foodstuffs. See abstract, col.1 lines 5-26, and claims 1-7. Jandacek also discloses that this edible oil composition comprises plant sterols (sterols and stanols) in 2.0-6.0% wt, which is known to inhibit or suppress cholesterol in the blood. See abstract, col.1-2, and Table 1 at col.3-4. Thus, Jandacek's edible oil inherently reduces total serum cholesterol and serum LDL cholesterol and raising HDL cholesterol in a human patient and also inherently reduces the synthesis, absorption and blood level of cholesterol and increases the excretion of cholesterol from the said human patient. Thus, Jandacek anticipates the claimed invention.

Applicant's remarks filed on August 26, 2002 in Paper No. 13 with respect to this rejection of claims 1-12 made under 35 U.S.C. 102(b) as being anticipated by Lowenstein of record stated in the Office Action dated February 26, 2002 have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art for the following reasons.

Applicants' arguments that Jandacek does not show or suggest an oil that reduces the synthesis, absorption and blood level of cholesterol and increases the excretion of cholesterol from the said human patient, are not found persuasive. Applicants are requested to note that the claiming of a new use, new function or unknown property which is inherently present in the prior art method will not make the claim patentable as set forth in the 102(b) rejection above. Moreover, the mechanism of action of a treatment does not have a bearing on the patentability of the invention even though applicant has proposed or claimed the mechanism (e.g., reducing the synthesis, absorption and blood level of cholesterol and increasing the excretion of cholesterol from the said human patient). Applicant's recitation of a new mechanism of action for the prior art method will not, by itself, distinguish the instant claims over the prior art teaching the same or nearly the same method steps. Mere recognition of latent properties in the prior art does not render novel or nonobvious an otherwise known invention. See *In re Wiseman*, 201 USPQ 658 (CCPA 1979).

Therefore, said rejection is adhered to.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 35, 37-43, and 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jandacek (3,865,939) and Imai et al. (5,514,398) and Lane et al. (5,591,772) for reasons of record stated in the Office Action dated February 26, 2002.

Applicant's remarks filed on August 26, 2002 in Paper No. 13 with respect to this rejection of claims 35, 37-43, and 47-48 made under 35 U.S.C. 103(a) of record in the previous Office Action dated February 26, 2002 have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art as discussed below.

Applicants argument that none of the cited prior art, alone or in combination, show an edible oil that not only reduces the synthesis, absorption and blood level of cholesterol but also increases the excretion of cholesterol from the said human patient. As discussed above, mere recognition of latent properties in the prior art does not render novel or nonobvious an otherwise known invention. See *In re Wiseman*, 201 USPQ 658 (CCPA 1979).

Further, since all active composition components herein are known to useful to treat and prevent hypercholesterol in human, it is considered prima facie obvious to combine them into a single composition to form a third composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

Therefore, motivation to combine the teachings of the prior art to make the present invention is seen. The claimed invention is clearly obvious in view of the prior art.

The following is a new rejection necessitated by Applicant's amendment filed on August 26, 2002 in Paper No. 13 wherein claims 52-61 are newly submitted.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 52-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jandacek (3,865,939) and Imai et al. (5,514,398) and Lane et al. (5,591,772).

Jandacek discloses that the edible oil therein is useful in a composition and a method of reducing total serum cholesterol and serum LDL cholesterol and raising serum HDL cholesterol in a human and that this edible oil in the composition with effective amounts of active ingredients is administered in the form of a food product such as cooking, salad oil or foodstuffs. See abstract, col.1 lines 5-26, and claims 1-7. Jandacek also discloses that this edible oil composition comprises plant sterols (sterols and stanols) in 2.0-6.0% wt, which is known to inhibit or suppress cholesterol in the blood. See abstract, col.1-2, and Table 1 at col.3-4.

Imai et al. discloses that sterols such as campesterol stigmasterol, sitosterol, and cycloarterol and triterpene alcohol is useful as food additives in a food composition (food product) and a method of reducing total serum cholesterol and serum LDL

cholesterol and raising serum HDL cholesterol in a human. Imai et al. also discloses that rice bran oil component is known to be useful in controlling blood cholesterol levels. See abstract, col.1 line 10-17, 33 to col.2 line 22, col. 22-26, and claim 3.

Lane et al. discloses that tocortrienols and tocortrienol-like compounds are useful as food additives in a food composition (foodstuff) and a method of decreasing total serum cholesterol and serum LDL cholesterol and raising serum HDL cholesterol in a human and tocortrienols and tocortrienol-like compounds also have antioxidant activity. See abstract and claims 8-11 and 21-25.

The prior art does not expressly disclose the employment of an oil comprising (1) about 10 to 30% of tocopherols, tocopherols or combinations; (2) about 2 to 20% of free sterols; (3) about 2 to 20% of sterol esters; (4) about 0.1 to 1.0% of cycloartenols, in the instant claimed method.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ an oil comprising (1) about 10 to 30% of tocopherols, tocopherols or combinations; (2) about 2 to 20% of free sterols; (3) about 2 to 20% of sterol esters; (4) about 0.1 to 1.0% of cycloartenols, in the claimed method herein.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ an oil comprising (1) about 10 to 30% of tocopherols, tocopherols or combinations; (2) about 2 to 20% of free sterols; (3) about 2 to 20% of sterol esters; (4) about 0.1 to 1.0% of cycloartenols, in the claimed method herein since each component in the oil and it's effective amount, e.g., tocopherols, tocopherols, free sterols, sterol esters, and cycloartenols are known to be useful as food additives in a

food composition (foodstuff) and a method of decreasing total serum cholesterol and serum LDL cholesterol and raising serum HDL cholesterol in a human based on the prior art. Therefore, one of ordinary skill in the art would have reasonably expected that combining these known ingredients known to be useful individually for the same purpose, i.e., decreasing total serum cholesterol and serum LDL cholesterol and raising serum HDL cholesterol in a human, in a composition to be administered would improve the therapeutic effect for treating hypercholesterol in human.

Since all active composition components herein are known to useful to treat and prevent hypercholesterol in human, it is considered prima facie obvious to combine them into a single composition to form a third composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Applicant's results in Example 2-4 of the specification at pages 19-23 have been fully considered with respect to the nonobviousness and/or unexpected results of the claimed invention but are not deemed persuasive for the following reasons. The results herein are not seen to provide clear and convincing evidence of nonobviousness or unexpected results over the cited prior art since the results from the testing on the employment of the oil herein do not show any additive effects on decreasing total serum cholesterol and serum LDL cholesterol and raising serum HDL cholesterol in a human.

Moreover, there is no clear and convincing side-by-side comparison with the closest prior art. Therefore, the evidence presented in specification herein is not seen to support the nonobviousness of the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.
Patent Examiner, AU 1617
November 5, 2002

SREENI PADMANABHAN
PRIMARY EXAMINER 11/16/02